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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/606,137 06/28/00 MOSELEY

M 500.003US1

EXAMINER

QM12/1003

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ART UNIT

PAPER NUMBER

3737

DATE MAILED:

10/03/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>09/606,137</p>	<p>Applicant(s)</p> <p>MOSELEY ET AL.</p>	
	<p>Examiner</p> <p>Jeoyuh Lin</p>	<p>Art Unit</p> <p>3737</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

-Claim 3 recites the limitation "the medical device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

-Claims 13-15 recites the limitation "said medical device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

-Claim 1, 2, 10, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Judd et al. (US 5,910,112).

Judd teaches a MRI imaging device for observing viability of heart cells, which could have come from a transplanted heart, comprising non-destructively monitoring Na-23 levels (column 3, lines 10-30).

-Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamelson (US 5,571,083).

Lamelson teaches a method and system for cell transplantation, comprising the use of MRI imager to guide and position a medical device (column 2, lines 30-67).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

-Claims 1, 2, 5-9, 12-16, and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wald (US 6,181,134 B1), and in view of Aebischer et al. (US 5,487,739).

Wald teaches an MRI imager for determining cell viability using a rf coil (column 4, line 25), comprising cell activity determination by observing lactate level (column 4, lines 60-65), as well as local concentration of NAA, choline, and creatine (column 5, lines 5-16) . However, it does not teach the use of the imager to observe transplanted cells. Aebischer teaches a method for cell transplantation, and suggests the use of an MRI imager to monitor the transplanted cell (column 5, line 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt the teachings of Aebischer et al. to Wald's device such that the use of the imager could be extended to post-transplanted observation viability.

-Claims 1, 2, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rockledge et al.

Rockledge teaches an MRI imager for determining cell viability by observing blood flow change and infusion of T1 shortening agent to increase contrast of T2 agent. (column 11, lines 15-20). However, it does not teach the use of the imager to observe

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transplanted cells. Aebischer teaches a method for cell transplantation, and suggests the use of an MRI imager to monitor the transplanted cell (column 5, line 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt the teachings of Aebischer et al. to Rocklage's device such that the use of the imager could be extended to post-transplanted observation viability.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Rocklage et al. (US 5,190,744) teaches methods for detecting blood perfusion and abnormality using MR imaging.

-Hochman et al. (US 6,196,226) teaches an NIR imager to detect neural tissue viability.

-Cabib et al. (US. 6,198,532 B1) teaches a spectral imager to inspect eye tissue viability.

-Jobsis (US 4,281,645) teaches spectrophotometric transillumination to monitor metabolism in body organs.

-Mayevsky (US 5,916,171) teaches NADH activity fluorescent imager which correlates NADH with blood flow.

-Morcos et al. (US 5,865,738) teaches a tissue viability monitor comprising NIR imager which observes cell metabolism.

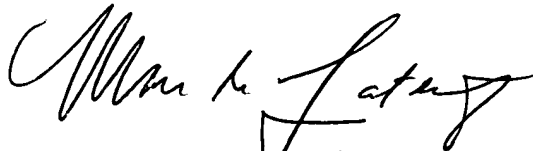
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeoyuh Lin whose telephone number is (703) 306-5990. The examiner can normally be reached on m-f, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JYL

JYL
October 1, 2001



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700